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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,888	10/06/2003	Nader Najafi	IB-12	3813

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EXAMINER	
BAXTER, ZOE E	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,888	NAJAFI ET AL.	
	Examiner	Art Unit	
	Zoe E. Baxter	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 and 25-33 is/are rejected.

7)☒ Claim(s) 24 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 06 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/06/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15 and 16 claim the monitoring system is incorporated into an open and closed loop system. The specification fails to define what the open and closed loop systems are. The failure of defining the open and closed loop systems renders the claims indefinite.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 11, 12, 21, 22, 24, 26 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The human body is considered non-statutory subject matter. Claims 11, 12, 21, 22, 24, 26 and 30 positively claim the human body therefore they are directed to non-statutory subject matter. It is recommended by the examiner to amend the claims such that the device is adapted to be inserted into the heart.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 6, 7, 9-13, 17-23, 25-27 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Govari et al. (US Patent No. 6636769 B2).

7. Referring to claim 1 Govari et al. teach a system for monitoring one or more physiological parameters for treatment of pulmonary hypertension within a patient (column 2 lines 29-33), said system comprising: one or more implantable sensing devices (column 2 lines 34-36), said sensing device comprising of at least one inductor coil (column 6 lines 22-25) and at least one sensor, with optional electronic components (column 5 lines 39-47); A non-implantable readout device (column 2 lines 43-44), said readout device comprising of at least one inductor coil allowing electromagnetic telecommunication and electromagnetic wireless powering (column 2 lines 59-65).

8. Referring to claim 6 Govari et al. teach a system for monitoring one or more physiological parameters wherein said physiological parameters include pressure (column 9 lines 17-30).

9. Referring to claim 7 Govari et al. teach a system for monitoring a physiological parameter wherein the sensing device measures the pressure in any of the chambers of the heart (column 10 lines 50-55).

10. Referring to claim 9 Govari et al. teach a system for monitoring a physiological parameter wherein the sensor is a passive sensor (column 8 lines 38-46). Govari et al. also teach the system uses a resonant circuit for the communication between the implantable device and the external reader (column 7 lines 58-67).

11. Referring to claim 10 Govari et al. teach a system for monitoring a physiological parameter wherein the physiologic parameter being measured is pressure (column 9 lines 17-30).

12. Referring to claim 11 Govari et al. teach a system for monitoring a physiological parameter wherein the implantable sensing device is fixed in a cavity of the heart (column 10 lines 50-55).

13. Referring to claim 12 Govari et al. teach a system for monitoring a physiological parameter wherein the implantable sensing device is fixed within the atrial septum (column 10 lines 56-60).

14. Referring to claim 13 Govari et al. teach a system for monitoring a physiological parameter wherein the system is used for disease management (column 10 lines 14-29).

15. Referring to claim 17 Govari et al. teach a system for monitoring a physiological parameter wherein said implantable sensing device is implanted using a surgical technique (column 11 line 49-column 12 line 19).

16. Referring to claim 18 Govari et al. teach a system for monitoring a physiological parameter wherein said implantable sensing device is implanted using a minimally invasive outpatient technique (column 11 lines 1-46).

17. Referring to claim19 Govari et al. teach a system for monitoring a physiological parameter wherein a catheter delivery method is used to implant said implantable sensing device (column 11 lines 1-46).

18. Referring to claim 20 Govari et al. teach a system for monitoring a physiological parameter, wherein said implantable sensing device uses anchoring mechanisms including but not limited to the use of helical threads for threading the sensor into the wall of the heart (column 3 lines 28-33), barbs for anchoring the sensor into the tissue (column 4 lines 53-59) and anchoring legs for anchoring the sensor to the tissue (column 4 lines 14-20).

19. Referring to claim 21 Govari et al. teach a system for monitoring a physiological parameter wherein said anchoring mechanism utilizes an anchor that passes through a septum wall and opens on one or both sides of a septal wall, clamping said implantable device to the wall (figure 11 and column 11 lines 42-47).

20. Referring to claim 22 Govari et al. teach a system for monitoring a physiological parameter wherein said anchoring mechanism utilizes an anchor that passes through the atrial septum (figure 11 and column 11 lines 42-47).

21. Referring to claim 23 Govari et al. teach a system for monitoring a physiological parameter wherein the anchoring method is similar to anchoring of septum occluder

devices, wherein two umbrella-shaped anchors one on each side which anchor the sensing device (figure 11).

22. Referring to claim 24 Govari et al. teach a system for monitoring a physiological parameter wherein the anchor passes through the atrial septum (figure 11) and comprises a larger and smaller portion (figure 11) and at least one sensor (column 5 lines 39-47). The larger portion of the implantable sensing device being located on the right side of the heart and the smaller portion of the implantable device being located on the left side of the heart in order to minimize the risk of thrombogenicity is intended use language. A recitation of the intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Govari et al. teaches a difference in size between the right and left sides of the implantable device therefore structurally the device is the same as the applicant's.

23. Referring to claim 25 Govari et al. teach a system for monitoring a physiological parameter wherein said anchoring mechanism is a helical screw (column 3 lines 28-33).

24. Referring to claim 26 Govari et al. teach a system for monitoring a physiological parameter wherein said anchoring mechanism is a tine that expands and catches on a tribeculated area of the heart (figure 11 and column 11 lines 42-47).

25. Referring to claim 27 Govari et al. teach a system for monitoring a physiological parameter wherein said anchoring mechanism is made from a nickel titanium alloy (column 6 lines 39-49).

26. Referring to claim 32 Govari et al. teach a system for monitoring a physiological parameter wherein at least a portion of said implantable sensing device is coated with one or more layers of thin coatings (column 6 lines 50-53).

27. Claims 1-3, 14, 30, 32 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al. (US Patent No. 7147604 B1).

28. Referring to claim 1 Allen et al. teach a system for monitoring a physiological parameter comprising: an implantable sensing device (column 3 lines 50-51), comprising at least one inductor coil (column 9 lines 12-33) and at least one sensor (column 3 lines 50-51); a non-implantable readout device comprising at least one inductor coil (column 14 lines 36-67).

29. Referring to claim 2 Allen et al. teach a system for monitoring a physiological parameter wherein said system is used for diagnosing pulmonary hypertension (column 1 lines 46-57).

30. Referring to claim 3 Allen et al. teach a system for monitoring a physiological parameter wherein said implantable sensing device comprises of at least one capacitive sensor (column 9 lines 46-55).

31. Referring to claim 14 Allen et al. teach a system for monitoring a physiological parameter wherein said readout device is capable of remote monitoring of patients with pulmonary hypertension including but not limited to home monitoring (column 1 lines 58-63).

32. Referring to claim 30 Allen et al. teach a system for monitoring a physiological parameter wherein delivery of said implantable sensing device is accomplished via

injection of said implantable sensing device into a large pulmonary artery, wherein blood flow delivers and anchors said implantable sensing device into one or more pulmonary artery with a smaller diameter (column 7 lines 40-48).

33. Referring to claim 32 Allen et al. teach a system for monitoring a physiological parameter wherein a portion of said implantable sensing device is coated with one or more layers of thin coatings (column 13 lines 61-67)

34. Referring to claim 33 Allen et al. teach a system for monitoring a physiological parameter wherein the coating material includes silicone (column 13 lines 61-67).

35. Claims 1, 4, 5, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Silver (US Patent No. 6442413 B1).

36. Referring to claim 1 Silver teaches a system for monitoring a physiological parameter comprising: an implantable sensing device (column 4 lines 64-67), comprising at least one inductor coil (column 15 line 59-column 16 line 30) and at least one sensor (column 4 lines 64-67); a non-implantable readout device comprising at least one inductor coil (column 15 line 59-column 16 line 30).

37. Referring to claim 4 Silver teaches a system for monitoring a physiological parameter wherein said implantable Sensing device includes a battery (column 11 lines 3-12).

38. Referring to claim 5 Silver teaches a system for monitoring a physiological parameter wherein said battery is rechargeable using wireless means (column 11 lines 3-12).

39. Referring to claim 28 Silver teaches a system for monitoring a physiological parameter wherein said implantable sensing device is augmented an actuator including a drug delivery pump (column 11 line 59-column 12 line 7).

40. Referring to claim 29 Silver teaches a system for monitoring a physiological parameter wherein said system is part of a closed-loop medical treatment system (column 11 line 59-column 12 line 7). When the system is used to automatically transfer a setting to the pump without any user input this is a closed loop system.

Claim Rejections - 35 USC § 103

41. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

42. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Govari et al. as applied to claim 1 above, and further in view of Salo et al. (US Patent No. 5417717). Govari et al. fail to teach a system for monitoring parameters for the treatment of pulmonary hypertension wherein the system calculates the change of pressure over time (dp/dt). Salo et al. teach the use of monitoring the change in pressure over time (column 7 lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Govari et al. to include a calculation of the change of pressure over time similar to that of Salo et al. in

order to provide an indicator of contractility of the heart (Salo et al. column 3 lines 39-41).

43. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Govari et al. as applied to claim 1 above, and further in view of Keren et al. (PG PUB US 2002/0173742 A1).

44. Referring to claim 15 Govari et al. fail to teach a system for monitoring parameters for the treatment of pulmonary hypertension wherein the system is incorporated into a closed-loop system with a right atrium to left atrium unidirectional valve. Keren et al. teach a closed-loop system which incorporates a sensor into a unidirectional valve system (page 5 paragraph 0028). A closed-loop system is being interpreted by the examiner to be one in which a feedback loop in the system would cause changes to the system. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Govari et al. to incorporate the system into a closed-loop system similar to that of Keren et al. in order to enable the valve to respond to conditions outside the heart (Keren et al. page 5 paragraph 0026).

45. Referring to claim 16 Govari et al. fail to teach a system for monitoring parameters for the treatment of pulmonary hypertension wherein the system is incorporated into an open-loop system with a right atrium to left atrium unidirectional valve. Keren et al. teach an open-loop system (page 5 paragraph 0028) which incorporates a sensor into a unidirectional valve system (page 5 paragraph 0028). An open-loop system is being interpreted by the examiner as: a system in which there is no feedback to the system being changed, for example a user changes the settings to a

fixed program. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Govari et al. to incorporate the system into an open-loop system similar to that of Keren et al. in order to enable the user to reprogram the implant (Keren et al. page 5 paragraph 0028)

46. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. as applied to claim 30 above, and further in view of Pathak et al. (US Patent No. 5662712). Allen et al. fail to teach a system for monitoring a physiological parameter wherein cell growth and encapsulation occurs over time. Pathak et al. teach a system comprising a sensor (column 11 lines 13-27) wherein cell growth and encapsulation occurs over time (column 6 lines 1-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Allen et al. to include the ability of the system to promote cell growth for encapsulation as suggested by Pathak et al. in order to better anchor the system to the vessel (Pathak et al. column 6 lines 1-23).

Conclusion

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735

ZEB